

Notice of Allowability

Application No.

09/976,059

Applicant(s)

FARNET ET AL.

Examiner

Lindsay Odell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 16 June 2005.
2. ☒ The allowed claim(s) is/are 25,26,31-34,40 and 42-59.
3. ☒ The drawings filed on 04 March 2005 and 10 February 2005 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 27 August 2004
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 6/16/05
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____



KATHLEEN KERR, PH.D.
PRIMARY EXAMINER

DETAILED ACTION

Application Status

1. In response to the previous Office action, a first action on the merits (mailed on September 9, 2004), Applicants filed a response and amendment received on February 10, 2005. Said amendment cancelled claims 1-24, 27-30, 35-39, 41 amended claims 25-26, 31-34, 40, 42 and 45 (claims 43 and 44 are original), and added new claims 46-59. Claims 25-26, 31-34, 40 and 42-59 are pending in this instant Office action.

Election

2. Applicant's election of SuperGroup A, SEQ ID NO: 15 (ORF 14), in the reply filed on February 27, 2004 is acknowledged. Affirmation of this election was not made by Applicant in replying to the Office action mailed on February 10, 2005. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The requirement is still deemed proper and is therefore made FINAL.

Priority

3. As previously noted, the instant application is granted the benefit of priority for the U.S. Provisional Application Nos. 60/239,924 and 60/283,296 filed on October 13, 2000 and April 17, 2001 as requested in the declaration and the first lines of the specification. The earliest priority document, 60/239,924, teaches SEQ ID NO:1.

The instant application is also granted the benefit of priority for the U.S. non-Provisional Application No. 09/910,813 filed on July 24, 2001 as requested in the declaration and the first lines of the specification. Since no mention of lineage is noted in the priority request, the instant application is considered a continuation-in-part of 09/910,813.

Information Disclosure Statement

4. As previously noted, the information disclosure statements filed on January 14, 2004 and February 27, 2004 has been reviewed, and their references have been considered as shown by the Examiner's initials next to each citation on the attached copy.

5. The information disclosure statements filed on August 27, 2004 has been reviewed, and their references have been considered as shown by the Examiner's initials next to each citation on the attached copy.

Compliance with the Sequence Rules

6. A substitute sequence listing correcting errors in the sequence listing submitted February 1-, 2005 was received and entered on April 11, 2005. A statement regarding the sameness of the paper copy of the sequence listing and the computer readable form (CRF) and no new matter was also received on April 11, 2005.

This application fully complies with the requirements of 37 C.F.R. § 1.821 through 1.825; by virtue of Examiner's amendment herein, Applicant's amendments to the specification and submission of a substitute sequence listing.

Withdrawn Objections to the Specification

7. The previous objection to the specification because the title is not descriptive is withdrawn by virtue of Applicant's amendment.
8. The previous objection to the specification because the Abstract does not completely describe the disclosed subject matter is withdrawn by virtue of Applicant's amendment.
9. The previous objection to the specification because Figure 2C contains a typographical error is withdrawn by virtue of Applicant's amendment.
10. The previous objection to the specification for having incomplete/unclear references as follows is withdrawn by virtue of Applicant's amendments.
11. The previous objection to the specification for unclear data in the table on pages 35-41 is withdrawn by virtue of Applicant's amendments.
12. The previous objection to the specification having an unclear amendment is withdrawn by virtue of Applicant's amendment.

Withdrawn Objections to the Claims

13. The previous objection of claims 25, 26, and 31-34 for containing non-elected subject matter is withdrawn by virtue of Applicant's amendments.

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14. The previous objection of claims 25, 26, 31-34, 37, 43, and 44 for having an improper Markush group are withdrawn by virtue of cancellation of the claim 29 and Applicant's amendments.

15. The previous objection of claims 26, 29, 31-34, and 37 as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn by virtue of cancellation of the claim 29 and Applicant's amendments.

16. The previous objection of Claim 40 for depending from an objected claim is withdrawn by virtue of Applicant's amendment.

Withdrawn Claim Rejections - 35 U.S.C. § 112

17. The previous rejection of claim 29 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase “an amino acid sequence of SEQ ID NO:15” (emphasis added) is withdrawn by cancellation of the claim.

18. The previous rejection of claim 42 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for since it depends from a cancelled claim is withdrawn by virtue of Applicant's amendment.

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19. The previous rejection of claims 31 and 32 under 35 U.S.C. § 112, first paragraph, new matter, as failing to comply with the written description requirement is withdrawn by virtue of Applicant's amendment.

EXAMINER'S AMENDMENT

20. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ywe J. Looper on June 16, 2005.

Amendment to the Specification

21. Amend the specification has been amended as follows:

a) Replace paragraph (0125) beginning at page 51, line 30, with the following replacement paragraph:

--- Figure 5B shows the local amino acid sequence homology between ORF 10 (SEQ ID NO: 11) and a key motif involved in coordinating an iron molecule in cytochrome P450 monooxygenases. The alignment depicts amino acids 405 to 452 of ORF 10 (SEQ ID NO: 11) and amino acids 370 to 421 of the consensus sequence for pfam00067, i.e. the cytochrome P450 motif (Bateman *et al.*, 2000, *Nucleic Acids Research*. Vol. 28, No. 1,

263-266). The region of ORF 10 (SEQ ID NO: 11) in highlight is in relatively good agreement with the Prosite motif PSO0086 required for binding iron (Hofmann *et al.*, 1999, *Nucleic Acids Research*, Vol. 27. No. 1, 215-219). Notably, the least variable positions of this motif are present in ORF 10 (SEQ ID NO: 11), i.e. residues Phe-423, Gly-425, Cys-428, and Gly-430). The C-terminal region of ORF 10 (SEQ ID NO: 11) contains a cluster of amino acid residues that shows significant local sequence homology to a motif frequently found in cytochrome P450 monooxygenases (the Cys-motif). This motif includes a cysteine residue that is highly conserved in the cytochrome P450 monooxygenases and that has been shown by X-ray crystal structure analysis to be involved in binding the iron metal cofactor required for catalysis. The Cys-motif of ORF 10 (SEQ ID NO: 11) is likely to contribute to the binding of a metal cofactor. The presence of two amino acid sequence motifs that are found in well-characterized metal-binding enzymes indicates that ORF 10 (SEQ ID NO: 11) is likely to be a metal-binding enzyme. Thus, the ORF 10 (SEQ ID NO: 11) is likely to be responsible for the formation of beta-hydroxyasparagine during the synthesis of ramoplanin.---

Amendments to the Claims

22. Replace claim 51 with the following replacement claim:

---Claim 51. The isolated nucleic acid of claim 47, wherein said nucleic acid comprises a coding sequence identical to or complementary to a nucleic acid selected from the group consisting of: nucleotides 42692-42898 of SEQ ID NO: 1; nucleotides 45836-46042 of SEQ ID NO:1; nucleotides 49001-49207 of SEQ ID NO:1; nucleotides 52118-

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52318 of SEQ ID NO:1; nucleotides 55310-55516 of SEQ ID NO:1; nucleotides 58553-58762 of SEQ ID NO:1; nucleotides 61742-61945 of SEQ ID NO:1 and nucleotides 64853-65059 of SEQ ID NO:1.---

Additional Comments

23. A statement certifying that all restrictions on accessibility to biological deposits 1090901-1, 1090901-2 and 10901-3, be irrevocably removed by Applicant upon the granting of the patent (see M.P.E.P. § 2404.01) was received and entered on June 16, 2005; therefore, the requirements to enable said deposits have been met by the instant application.

Conclusion

24. Claims 25-26, 31-34, 40 and 42-59 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsay Odell whose telephone number is 571-272-3445. The examiner can normally be reached on M-F, 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lindsay Odell, Ph.D.
June 27, 2005


KATHLEEN KERR, PH.D.
PRIMARY EXAMINER